

REMARKS

The above-identified application has been carefully reviewed in light of the Examiner's communication mailed September 8, 2004.

Applicant wishes to advise the Examiner that Allergan, Inc., the parent of the assignee of the above-identified application, commercially launched a product, under the trademark Refresh Liquigel, which is covered by one or more of the claims of this application less than one year prior to the filing date of this application. This product was identified as Liquigel in the "Abstract Submitted to ARVO for Conference held 11/30/01: The Effect of Different CMC Materials in Artificial Tears in the Tear Layer on Contrast Sensitivity" which was submitted to the Patent and Trademark Office with an Information Disclosure Statement filed March 20, 2002.

Since the initial commercial launch of the Refresh Liquigel product occurred less than one year prior to the filing date of the above-identified application, applicant submits that such commercial activity is not prior art with respect to this application and does not adversely impact the patentability of the present claims.

In order to facilitate the prosecution of the above-identified application, claims 1 and 20 have been amended to clearly identify the first and second polyanionic component portions as being selected from anionic cellulosic derivatives and mixtures thereof. In addition, claims 5 to 8, 10, 26, 27 and 29 have been canceled, without prejudice. These amendments are fully supported by the present specification, and include no new matter.

Claims 1 to 34 have been rejected under 35 U.S.C. 103 as being unpatentable over Dikstein and further over Bhagat. Applicant disagrees with the Examiner's position with regard to claims 1 to 34. However, in order to facilitate prosecution of this application, applicant has amended the claims as noted above. Applicant expressly reserves the right to seek patent protection for the other subject matter set forth in claims 1 to 34 in one or more later filed related applications.

Applicant traverses the rejection as it pertains to the present claims 1 to 4, 9, 11 to 25, 28 and 30 to 34.

The present claims are directed to ophthalmic compositions comprising an ophthalmically acceptable carrier component and a polyanionic component.

In independent claim 1, the polyanionic component includes a first polyanionic component portion having a first molecular weight and a second polyanionic component portion having a second, different molecular weight. The first and second polyanionic component portions are each present in an amount effective to provide lubrication to an eye when the composition is administered to the eye.

In independent claim 20, the polyanionic component includes at least two polyanionic component portions. Each of the at least two polyanionic component portion has a different molecular weight and is present in an amount of at least about 0.1% (w/v) of the composition.

In the above independent claims, the first and second polyanionic component portions (claim 1) and the at least two polyanionic component portions (claim 20) are selected from anionic cellulosic derivatives and mixtures thereof.

The present compositions provide effective lubrication to eyes, for example, eyes suffering from "dry eye" syndrome. The present compositions are relatively straightforward, can be easily and cost effectively manufactured and can be used much like prior art eye lubricating materials. Importantly, the present compositions include combinations of different molecular weight anionic cellulosic derivatives and preferably provide relatively long lasting, effective eye lubrication, for example, without the need for very frequent readministration or replenishment to the eye, and advantageously without being unduly disruptive to clear vision from the eye being treated. See Examples 1 to 10 in the above-identified application.

Dikstein discloses isotonic humectant eyedrops which have non-Newtonian rheological properties, simulating the rheological

behavior of human tears. Dikstein discloses that the eye drops include the essential components of water, an anionic polymer having a molecular weight in the 500,000 to about 4,000,000 range and a low molecular weight humectant polyol at a concentration of about isotonicity or slightly above. In the examples, Dikstein discloses combinations of glycerol together with sodium hyaluronate, polyacrylate, and a combination of polyacrylate and sodium hyaluronate.

Dikstein does not disclose, teach or suggest the present invention. For example, Dikstein does not disclose, teach or even suggest an ophthalmic composition comprising an ophthalmically acceptable carrier component and a polyanionic component including a first polyanionic component portion and a second polyanionic component portion, or at least two polyanionic component portions, with each of the polyanionic component portions having a different molecular weight and being selected from anionic cellulosic derivatives and mixtures thereof, as recited in the present claims.

In addition, none of the examples of Dikstein disclose, teach or even suggest a composition as recited in the present claims. For example, none of the examples of Dikstein disclose, teach or even suggest any anionic cellulosic derivative, let alone two anionic cellulosic derivative portions having different molecular weights, as recited in the present claims.

Bhagat discloses physiological tear compositions for the treatment of dry eye syndrome having high viscosity and containing bicarbonate which include a cellulosic polymer and a carboxy vinyl polymer. Bhagat discloses that preferred cellulosic polymers include hydroxypropyl methyl cellulose (HPMC), hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC) and methyl cellulose (MC).

Bhagat does not disclose, teach or suggest the present invention. For example, Bhagat does not disclose, teach or even suggest a composition comprising an ophthalmically acceptable carrier component and a polyanionic component including a first polyanionic component portion and a second polyanionic component

portion selected from the group consisting of anionic cellulosic derivatives and mixtures thereof in which the first and second polyanionic component portions have different molecular weights. Bhagat does not disclose or suggest any anionic cellulosic derivatives, let alone first and second anionic cellulosic derivative portions having different molecular weights, as recited in the present claims. Further, the fact that Bhagat discloses a preference for cellulosic polymers which are not anionic actually teaches away from the present invention.

Clearly, each of Dikstein and Bhagat is deficient with regard to the present claims. Neither Dikstein nor Bhagat disclose, teach or even suggest any composition having two anionic cellulosic derivative portions of different molecular weights, as recited in the present claims. Only after knowing of the above-identified application would one of ordinary skill in the art modify the teachings of Dikstein and Bhagat to include first and second polyanionic component portions or at least two polyanionic component portions selected from anionic cellulosic derivatives and mixtures thereof with each component portion having a different molecular weight, as recited in the present claims, and obtain a substantial and important advantages achieved by applicant. Dikstein discloses compositions including only a single portion of other, different polyanionic components and, thus, actually teaches away from compositions including first and second portions or at least two portions of a polyanionic component selected from anionic cellulosic derivatives and mixtures thereof having different molecular weights, as recited in the present claims. Bhagat does not disclosure or even suggest any anionic cellulosic derivatives, let alone two anionic cellulosic derivative portions having different molecular weights, as recited in the present claims.

In view of the above, applicant submits that the present claims, that is claims 1 to 4, 9, 11 to 25, 28 and 30 to 34, are unobvious from and patentable over Dikstein and further over Bhagat under 35 U.S.C. 103 (a).

Each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art, taken singly or in any combination, disclose, teach or even suggest the compositions including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims are unobvious from and patentable over the prior art under 35 U.S.C. 103(a). Therefore, applicant submits that claims 1 to 4, 9, 11 to 25, 28 and 30 to 34, are allowable and respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Respectfully submitted,



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